AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,859	02/26/2002	Joseph Altin	EM436365176US	8566

7590 12/29/2005

Dorsey & Whitney
250 Park Avenue
New York, NY 10177

EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,859	ALTIN ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

16-20, 22, 36-39 J.E.

4)☒ Claim(s) 1,2,4,5,7,8,10-15,21 and 23-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

16-20, 22, 36-39 J.E.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1, 2, 4, 5, 7, 8, 10-15, 21, and 23-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Note: Change in Art Unit, SPE, and Examiner

1. The application has been reassigned to a new examiner in Art Unit 1633. Therefore, future correspondence should reflect such changes. The information regarding the Examiner, SPE and Art Unit is at the end of the Action.

Upon review of the prosecution history in this application, the Office has determined that it is necessary to vacate the previous restriction requirement and Office Action. In order for examination to further proceed expeditiously and with high quality, a new restriction requirement is necessary as set forth below. The Office regrets any inconvenience this may cause the Applicant.

2. Claims 3, 6, and 9 have been cancelled. Claims 16-20, 22, and 36-39 have been withdrawn.

Claims 1, 2, 4, 5, 7, 8,10-15, 21, and 23-35 are pending.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 4, 5, 8, 10-15, 21, and 23-35, drawn to a method of modifying intact cells for the purpose of altering immunity or for targeting of drugs and other agents to a specific cell type or tissue.

Group II, claims 1, 2, 4, 5, 7, 8, 10-15, 21, and 23-35, drawn to a method of modifying intact biological membrane that are not intact cells or liposomes, for the purpose of altering immunity or for targeting of drugs and other agents to a specific cell type or tissue.

Group III, claims 1, 2, 4, 5, 7, 8, 10-15 and 30-35, drawn to a method of modifying liposomes for the purpose of altering immunity or for targeting of drugs and other agents to a specific cell type or tissue.

Group IV, claims 1, 2, 4, 5, 7, 8, 10-15 and 30-35, drawn to a method of modifying synthetic membranes for the purpose of altering immunity or for targeting of drugs and other agents to a specific cell type or tissue.

The groups listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons: cells comprise many structural elements and biological properties not shared with liposomes, synthetic membranes or membranes that may be derived from the cells; further, cells cannot be made and must be isolated from a living organism, whereas synthetic membranes and liposomes can be generated in a test tube. In addition, the chemical components of each group can comprise substantially different elements. As such, the search for each species is not co-extensive and would place an undue burden on the examiner.

4. Should invention I be elected for prosecution, species restriction to one of the following is required under 35 U.S.C. 121 and 372:

This application contains claims directed to the following patentably distinct species of the claimed invention:

- modifying immunity to tumors, modifying any biological response, or treatment of any disease condition (claim 24);
- receptor or ligand (claim 25);
- ligand, receptor, recombinant protein, polysaccharide, glycoprotein, or antigen (claim 29);
- recombinant polypeptide, co-stimulatory molecule, therapeutic drug or nucleic acid molecule (claim 32);
- receptor, ligand, glycoprotein, polysaccharide, or recombinant polypeptide (claim 33).

Applicant is required to elect a single disclosed species from each group of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Should invention II be elected for prosecution, species restriction to one of the following is required under 35 U.S.C. 121 and 372:

This application contains claims directed to the following patentably distinct species of the claimed invention:

- soinication or extrusion/filtration (claim 7);
- modifying immunity to tumors, modifying any biological response, or treatment of any disease condition (claim 24);
- receptor or ligand (claim 25);
- ligand, receptor, recombinant protein, polysaccharide, glycoprotein, or antigen (claim 29);
- recombinant polypeptide, co-stimulatory molecule, therapeutic drug or nucleic acid molecule (claim 32);
- receptor, ligand, glycoprotein, polysaccharide, or recombinant polypeptide (claim 33).

Applicant is required to elect a single disclosed species from each group of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Should invention III or invention IV be elected for prosecution, species restriction to one of the following is required under 35 U.S.C. 121 and 372:

This application contains claims directed to the following patentably distinct species of the claimed invention:

- sonication or extrusion/filtration (claim 7);
- recombinant polypeptide, co-stimulatory molecule, therapeutic drug or nucleic acid molecule (claim 32);
- receptor, ligand, glycoprotein, polysaccharide, or recombinant polypeptide (claim 33).

Applicant is required to elect a single disclosed species from each group of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The species listed above do not relate to a single inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2 the species lack the same or corresponding special technical feature for the following reasons:

Sonication and extrusion/filtration are substantially different techniques. Modifying immunity to tumors, modifying any biological response, or treatment of any disease condition are targeted towards distinct processes and search for one species is

not co-extensive and would place an undue burden on the examiner. Ligand, receptor, recombinant protein, polysaccharide, glycoprotein, or antigen are all substantially different compositions with different structural and biochemical properties, and which have substantially different functions. Similarly, recombinant polypeptide, co-stimulatory molecule, therapeutic drug or nucleic acid molecule represent genuses of molecule that are substantially different in physical , chemical and functional properties.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ileana Popa

Janet L. Epps for
Primary AU 1633